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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,027	05/14/2001	Bernhard Hering	1432.05US02	7980

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PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/28/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,027

Applicant(s)

HERING ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 3-79 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-39 and 45-64 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 65-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicant's amendment, filed 12/11/02 (Paper No. 16), is acknowledged.

It is noted that since there were no changes made in pending claims 40- 44 and during the telephone interview with Curtis B. Herbert on 01/16/03 applicant confirmed that there was no intention to make any changes in said claims, the request to substitute said claims was not entered. Also, if applicant intends to cancel claims 1, 3-39 and 45-64, applicant should clearly indicate this cancellation in an amendment to the claims, but not in the remarks.

Claims 1 and 3-79 are pending.

Applicant's election without traverse of Group V, claims 40-44, now claims 40-44 and 65-79, in Paper No. 16 is acknowledged.

Claims 1, 3-39 and 45-64 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 40-44 and 65-79 are under consideration in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.
3. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).
4. Formal drawings have been submitted on 01/23/02. However, it is noted that only figure 1 to 6 were submitted, while brief description of drawing discloses 16 figures and 16 informal figures were originally submitted on 05/14/01.
5. Applicant is advised that should claim 40 be found allowable, claim 67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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In the instant case claim 40 recites "infusing donor cells within 96 hours of the pancreatic islet cell transplant" and claim 67 recites "donor cell infusion is performed after the pancreatic islet cell transplant". One of ordinary skill in the art would interpret the phrase "within 96 hours of the pancreatic islet cell transplant" as "after the pancreatic islet cell transplant".

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 40-44 and 65-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 40 is indefinite and ambiguous in the recitation of "administering a pancreatic islet cell transplant" in line 3 ; "infusing donor cells" in line 6 ; and "mildly myeloablative" in line 10.

It is improper to recite "administering a pancreatic islet cell transplant". It is suggested that said phrase be change to "transplanting pancreatic islet cells".

Also, it is improper to recite "infusing donor cells". It is suggested that said phrase be change to "performing a donor bone marrow cell transplant" for clarity and consistency with the disclose of the specification.

In addition, the characteristics and metes and bounds of "mildly myeloablative" are unclear and indefinite and not define by the specification.

B. Claim 42 is indefinite and ambiguous in the recitation of "donor chimerism level". It is unclear what applicant mean by "donor chimerism"?

C. Claim 43 is indefinite and ambiguous in the recitation of "administering a cell pretreatment from the donor to the recipient". The characteristics and metes and bounds of "pretreatment" are unclear and indefinite and not define by claims or specification as originally filed. Also, it is unclear who's cells donor or recipient are pretreated?

D. It is improper to recite "pretreating the recipient with pretreatment cells" in claim 68. It is suggested that said phrase be change to "pretreating the recipient with pretreated cells. Also it is unclear what type of donor cell (pancreatic islet cells or the one that produces the immune system in recipient) are pretreated?

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E). Dependent claim 79 recited "low-dose total body irradiation". There is insufficient antecedent basis for this limitation in the claims, since base Claim 78 does not recite "total body irradiation".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 42-44 and 65-73 and 75-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

The claimed method of transplanting pancreatic islet cells from donor to a recipient, wherein : 1) donor chimerism level in the recipient of at least 15 % is achieved, claimed in Claim 42; 2) administering a cell pretreatment from the donor to the recipient prior to the infusion of the donor cells, claimed in claim 43; 3) administering an antilymphocyte serum within 48 h after an end of the cell pretreatment, claimed in Claim 44; 4) the donor is a clinical cadaver and the pancreatic islet cell transplant, conditioning treatment and the infusion of the donor cells are completed within a single forty-eight hour, claimed in claim 65; 5) conditioning treatment is accomplished such that an amount of granulocytes in the recipient blood decrease by less than 30 %, claimed in Claim 66; 6) the donor cell infusion is performed after the pancreatic islet cell transplant, claimed in claim 67; 7) pretreating the recipient with pretreatment cell from the donor prior to the infusion of the donor cells, claimed in Claim 68; 8) conditional treatment is accomplished by administering at least one drug, chosen from the group recited in claims 69 and 70; 9) administering the immune blockade treatment is accomplished by administering at least one of the compound selected from the group recited in Claim 71; 10) conditional treatment is started less than six days prior to the infusion of donor cells, claimed in Claim 72; 11) conditional treatment is started less than two days prior to the infusion of donor cells, claimed in Claim 73; 12) donor cell infusion is performed by administering stem cells, claimed in Claim 75; 13) donor cell infusion includes administering the stem cells to the recipient on more than one day, claimed in Claim 76; 14) donor cell infusion includes administering stem cells to the recipient that are collected from peripheral blood of the donor, claimed in Claim 77; 15) conditional treatment includes low-dose irradiation of less than 500 GY, claimed in Claim 78; 16) conditional treatment includes low-dose total body irradiation of less than 300 GY, claimed in Claim 79 represent a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come from.

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The specification and the claims as originally filed only support a method of transplanting pancreatic islet cells from donor to a recipient, wherein : 1) the method steps recited in Claim 40, 2) the donor cell infusion and the pancreatic islet cell transplant both occur within a twelve hour, claimed in Claim 41; 3) the donor cell infusion is performed by administering bone marrow from the donor to the recipient, claimed in Claim 74.


10. Claims 40-44 and 65-79 are free of the prior art.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
January 27, 2003.


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600